

Notice of Allowability

Application No.

10/642,284

Examiner

ANNE L. HOLLERAN

Applicant(s)

KUMAGAI ET AL.

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/10/2009.
2. ☒ The allowed claim(s) is/are 22,24,25 and 27-32.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date <u>20090617</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Linda Parker on June 22, 2009.

The application has been amended as follows:

In the claims:

Claim 28. A humanized diabody-type bispecific antibody selected from the group of ~~(A)-(D)~~ consisting of:

(A) a first single-chain polypeptide comprising
a heavy chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:43, and a light chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:46, and

a second single-chain polypeptide comprising
a light chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:44, and a heavy chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:45,

Art Unit: 1643

B) a first single-chain polypeptide comprising
a heavy chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:43 and a light chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:46, and

a second single-chain polypeptide comprising a light chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:44 and a heavy chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:45, wherein Met at position 48 and Ala at position 93 of the heavy chain sequence according to SEQ ID NO:45 are replaced by Ile and Thr, respectively,

(C) a first single-chain polypeptide comprising
a heavy chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:43 and a light chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:46, and

a second single-chain polypeptide comprising
a light chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:44 and a heavy chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:45, wherein Arg at position 66, Met at position 69, Arg at position 71 and Thr at position 73 of the heavy chain sequence according to SEQ ID NO:45 are replaced by Lys, Leu, Val and Arg, respectively, and

(D) a first single-chain polypeptide comprising

Art Unit: 1643

a heavy chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:43 and a light chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:46, and

a second single-chain polypeptide comprising a light chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:44 and a heavy chain comprising a variable region comprising the amino acid sequence according to SEQ ID NO:45, wherein Met at position 48, Arg at position 66, Met at position 69, Arg at position 71, Thr at position 73 and Ala at position 93 of the heavy chain sequence according to SEQ ID NO:45 are replaced by Ile, Lys, Leu, Val, Arg and Thr, respectively.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran

Patent Examiner

June 22, 2009

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643